

Modifications to ScoutPro Accessories

Special 510(k) Premarket Notification

MAY - 7 2008

K080988

1. 510(K) SUMMARY

Name and Address of Sponsor:

BIOTRONIK, Inc.
6024 Jean Road
Lake Oswego, OR 97035

Establishment Registration Number:

1028232

Device Name:

Proprietary Name:	ScoutPro 8F
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX
Proprietary Name:	ScoutPro 7F
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX
Proprietary Name:	ScoutPro Slitter Tool Advanced
Classification:	Class II (21 CFR 870.1250; 870.1310; 870.1330)
Classification Name:	Wire, Guide, Catheters, Percutaneous
Product Code:	DQY, DRE, DQX

General Description:

The ScoutPro family of introducer systems and accessories is specifically used for the placement of coronary sinus leads. It is designed to assist with introducing leads into the vessels of the left side of the heart via the coronary sinus. The system also facilitates access to the coronary sinus venous system as well as probing the coronary sinus. The following ScoutPro accessories are subject to this Special 510(k):

The following ScoutPro 8F accessories were cleared under 510(k) #K060655 on April 4, 2006:

The basic set ScoutPro 8F contains the following components:

- 1 hemostatic valve
- 2 guiding catheters "BIO1" and "BIO2"
- 1 dilator for the guiding catheter
- 1 peel-away sheath 11F with dilator
- 1 guidewire
- 1 needle
- 1 syringe
- 2 slitter tools 4.9 F and 6.3 F for different lead sizes

ScoutPro Sheath "Hook" contains the following components:

- 1 guiding catheter "Hook"
- 1 dilator for the guiding catheter.

ScoutPro Sheath "Multi-Purpose Hook" contains the following components:

- 1 guiding catheter "Multi-Purpose Hook"
- 1 dilator for the guiding catheter

ScoutPro Sheath "Amplatz 6.0" contains the following components:

- 1 guiding catheter "Amplatz 6.0"
- 1 dilator for the guiding catheter

The following ScoutPro 7F accessories were cleared under 510(k) #K060807 on April 24, 2007:

The basic set **ScoutPro 7F** contains the following components:

- 1 hemostatic valve
- 2 guiding catheters "MPEP" and "BIO2"
- 1 dilator for the guiding catheter
- 1 peel-away sheath 10F with dilator
- 1 guidewire
- 1 needle
- 1 syringe
- 2 slit tools 4.9 F and 6.3 F for different lead sizes
- **ScoutPro 7F Sheath "Hook"** contains the following components:
 - 1 guiding catheter "Hook"
 - 1 dilator for the guiding catheter
- **ScoutPro 7F Sheath "Multi-Purpose Hook"** contains the following components:
 - 1 guiding catheter "Multi-Purpose Hook"
 - 1 dilator for the guiding catheter
- **ScoutPro 7F Sheath "Amplatz 6.0"** contains the following components:
 - 1 guiding catheter "Amplatz 6.0"
 - 1 dilator for the guiding catheter
- **ScoutPro Hemostatic Valve**
- **ScoutPro Slitter Tool**

The following ScoutPro accessory was cleared under 510(k) #K071665 on July 18, 2007:

- **ScoutPro Slitter Tool Advanced**

The following ScoutPro accessories were cleared under 510(k) #K072329 on March 25, 2008:

- **ScoutPro 7F Sheath "Extended Hook"** contains the following components:
 - 1 guiding catheter "Extended Hook"
 - 1 dilator for the guiding catheter
- **ScoutPro 7F Sheath "Extended Hook Right"** contains the following components:
 - 1 guiding catheter "Extended Hook Right"
 - 1 dilator for the guiding catheter

- **ScoutPro 7F Sheath "MPEP"** contains the following components:
 - 1 guiding catheter "MPEP"
 - 1 dilator for the guiding catheter
- **ScoutPro 7F Sheath "BIO2"** contains the following components:
 - 1 guiding catheter "BIO2"
 - 1 dilator for the guiding catheter
- **ScoutPro Guidewire**

Device Modifications:

All ScoutPro 8F guiding catheters will utilize a new shaping process and an additional supplier of the internal braided tubing, made out of PEBAX. No changes have been made to the chemical or physical composition of the PEBAX, only the supplier of the tubing. The additional supplier for the braided tubing will be Quan Emerteq, while the original ScoutPro 8F guiding catheters were supplied by TFX Medical. Both suppliers may be used in the future and they both receive the PEBAX raw material and manufacture the tubes to the same specifications. As with the material from the original supplier, BIOTRONIK receives the tubes, adds the white tip and grip, and creates the shape.

These changes affect the ScoutPro 8F guiding catheters "BIO1" and "BIO2" included in the ScoutPro 8F kit, as well as the separately available "Hook," "Multipurpose Hook" and "Amplatz 6.0." The same shaping process and additional supplier of the PEBAX was cleared for the ScoutPro 7F guiding catheters in #K072329, dated March 25, 2008.

The usage of the ScoutPro 8F kit as well as all the ScoutPro 8F guiding catheters remains unchanged and the product characteristics such as indications for use, contraindications, and functions are identical to the previously cleared ScoutPro accessories in submission #K060655, cleared on April 4, 2006. Therefore, the previously cleared versions will serve as predicate devices for the modified products included in this Special 510(k).

Minor modifications were made to the ScoutPro accessories since the last 510(k) clearance including an update to the non-lingual labeling and technical manuals, a change in the tensile test procedure and a clarification of the blade angle for the ScoutPro Slitter Tool Advanced.

Predicate Devices:

BIOTRONIK proposes the following delivery systems cleared through 510(k) notification as the predicate devices for the modified ScoutPro 8F guiding catheters and accessories described in this Special 510(k):

- BIOTRONIK's ScoutPro 8F (#K060655, cleared on April 4, 2006)
- BIOTRONIK's ScoutPro 7F (#K060807, cleared on April 24, 2006)
- BIOTRONIK's ScoutPro Slitter Tool Advanced (#K071665, cleared on July 18, 2007)
- BIOTRONIK's ScoutPro Modifications to Accessories (#K072329, cleared on March 25, 2008)

Indications for Use:

The ScoutPro CS Lead Introducer System facilitates lead implantation in the left of the heart via the coronary sinus.

The ScoutPro accessories are used in conjunction with the ScoutPro CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

Name and Address of Manufacturer: BIOTRONIK GmbH & Co. KG
Woermannkehre 1,
12359 Berlin, Germany
011-49-30-689-05-1210

Manufacturer's Registration Number: 9610139

Name and Address of Contract Manufacturer: BIOTRONIK AG
Ackerstraße 6
8180 Bülach, Switzerland
011-41-44-864-5169

Contract Manufacturer's Registration Number: 8043892

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
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MAY - 7 2008

BIOTRONIK, Inc.
c/o Mr. Jon Brumbaugh
Vice President, Regulatory Affairs and Compliance
6024 Jean Road
Lake Oswego, OR 97035

Re: K080988
ScoutPro 8F, ScoutPro 7F, ScoutPro Slitter Tool Advanced
Regulation Number: 21 CFR 870.1250; 870.1310; 870.1330
Regulation Name: Wire, Guide, Catheters, Percutaneous
Regulatory Class: Class II (two)
Product Code: DQY, DRE, DQX
Dated: April 4, 2008
Received: April 7, 2008

Dear Mr. Brumbaugh:

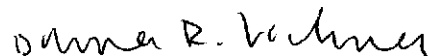
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

K080988

Device Name:

ScoutPro 8F CS Lead Introducer System

ScoutPro Sheath "Hook"

ScoutPro Sheath "Multi-Purpose Hook"

ScoutPro Sheath "Amplatz 6.0"

Indications for Use:

The ScoutPro CS Lead Introducer System facilitates lead implantation in the left of the heart via the coronary sinus.

The ScoutPro accessories are used in conjunction with the ScoutPro 8F CS Lead Introducer System to facilitate lead implantation in the left of the heart via the coronary sinus.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use ☐
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Danna R. Volchek
(Division Sign-Off)
Division of Cardiovascular Devices

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